UC Irvine
Education and Guidance Documents

Title

Protocol *Regulatory and Internal Congruence Worksheet*

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Copyright Information

EQUIP — Education & Quality Improvement Program

Title: Protocol *Regulatory and Internal Congruence Worksheet*
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Audience: Researchers

POPULATION (and if applicable: phase, sub-study, etc)	AIMS OUTCOMES	AGE GROUP SAMPLE SIZE CRITERIA	RECRUITMENT ❑ Source ❑ Methods ❑ Screening ❑ N/A	CONSENT ❑ Verbal, Written, Waiver, Assent ❑ Process of Consent ❑ HIPAA Authorization ❑ Other Permissions ❑ Study Transfer Considerations	STUDY DESIGN PROCEDURES MEASURES ❑ List procedures, measures, data being collected ❑ Location for each procedure ❑ Costs, billing	RISKS: PROCEDURES, PRIVACY, CONFIDENTIALITY/STORAGE, DATA RETENTION, SHARING OF DATA, FUTURE USE ❑ Consider population, age group, research procedure(s), data, specimen; and minimizing each risks; ancillary committee reviews (where applicable) ❑ Agreements (sharing / privacy) ❑ International considerations ❑ EU GDPR Policy ❑ OIT Considerations *	❑ INTERNAL CONGRUENCE BETWEEN ALL DOCUMENTS
Population 1						*UCI OIT: Policies, Data Classification (P4 level data that are collected, used, and stored, require an OIT risk assessment), Research Services, Cloud Services, Protecting University Data*	❑ Aims / Outcomes ❑ Population ❑ Recruitment ❑ Consent / HIPAA ❑ Design / Procedures ❑ Risks ❑ *Documentation:* recruitment, consent/HIPAA, source documents, supporting materials, site-permissions, permissions to access data/materials, copy of service/purchase agreements, copy of off-site collection/storage confidentiality terms/agreements, appendices, etc
Population 2						*UCI OIT: Policies, Data Classification (P4 level data that are collected, used, and stored, require an OIT risk assessment), Research Services, Cloud Services, Protecting University Data*	

Ensure congruence is achieved within each core element

Aims

Outcomes

Study Design
Population/Criteria/Accrual
Screening/Recruitment (RP)
Procedures / Location (RP)
Costs / Billing
Measures / Data

Consent (RP)
HIPAA Authorization
Other Permissions
Study Transfer
Considerations

Risks (procedures / data)
Privacy (subject)
Confidentiality/Storage (data)
Sharing/Retention/Future Use
Agreements (sharing/privacy)
International Considerations